

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD., Plaintiff,)	
)	
)	C.A. No. 21-1015 (GBW)
v.)	
)	DEMAND FOR JURY TRIAL
SAREPTA THERAPEUTICS, INC.,)	
Defendant.)	
SAREPTA THERAPEUTICS, INC. and THE)	
UNIVERSITY OF WESTERN AUSTRALIA,)	
Defendant/Counter-Plaintiffs,)	
)	
v.)	
)	
NIPPON SHINYAKU CO., LTD. and NS)	
PHARMA, INC.,)	
Plaintiff/Counter Defendants.)	

**PLAINTIFF’S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR
PARTIAL SUMMARY JUDGMENT NO. 2 REGARDING
INFRINGEMENT OF CERTAIN NS PATENTS**

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Defendant NS Pharma, Inc.*

Dated: December 11, 2023

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I INTRODUCTION

The Court should grant summary judgment in favor of plaintiff Nippon Shinyaku Co., Ltd. (“NS”) regarding its claims that defendant Sarepta Therapeutics, Inc. (“Sarepta”) (i) directly and indirectly infringes claims 1-3 of US Patent No. 10,385,092 (the “’092 Patent”), claims 1-2 of US Patent No. 10,407,461 (the “’461 Patent”), and claims 1-2 of US Patent No. 10,487,106 (the “’106 Patent”) (collectively, the “NS Product Claims”) under 35 U.S.C. § 271 (a), (b), and (c); and (ii) indirectly infringes claims 1-12 of US Patent No. 10,647,741 (the “’741 Patent”) and claims 1-4 of US Patent No. 10,662,217 (the “’217 Patent”) (collectively, the “NS Method of Use Claims”) under 35 U.S.C. § 271 (b) and (c).. No factual disputes remain on this claim.

II NATURE AND STAGE OF THE PROCEEDINGS

NS incorporates its statement regarding the nature and stage of the proceedings from its Motion for Partial Summary Judgment No. 1 Regarding Invalidity of the UWA Patents.

III CONCISE STATEMENT OF FACTS

NS incorporates by reference its concise statement of facts (“SOF”) filed herewith.

IV SUMMARY OF THE ARGUMENT

The Court should grant partial summary judgment in favor of NS regarding (i) direct and indirect infringement of the NS Product Claims and indirect infringement of the NS Method of Use Claims because the undisputed evidence shows that Sarepta infringes the claims and Sarepta has not identified any factual or legal argument rebutting said infringement.

V LEGAL STANDARD

NS incorporates its legal standard from its Motion for Partial Summary Judgment No. 1.

VI ARGUMENT

In a patent case, “[a]n infringement issue is properly decided upon summary judgment when no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused [products] either literally or under the doctrine of equivalents.” *Gart*

v. Logitech, Inc., 254 F.3d 1334, 1339 (Fed. Cir. 2001). Here, there is no factual dispute regarding Sarepta's Vyondys 53[®] (golodirsen) product and Sarepta has provided no relevant non-infringement positions. Summary judgment of infringement is warranted.

A. Sarepta Directly Infringes the NS Product Claims

A party directly infringes a patent when it “makes, uses, offers to sell, or sells any patented invention, within the United States.” 35 U.S.C. § 271(a). Here, it is undisputed that Sarepta's Vyondys 53[®] (golodirsen) product meets each and every limitation of the NS Product Claims. SOF ¶ 21; *see also* SOF ¶¶ 5-10. Sarepta has not identified any limitation of the NS Product Claims that golodirsen does not meet. SOF ¶ 22. It is also undisputed that Sarepta sells and offers to sell Vyondys 53[®] (golodirsen) in the United States. SOF ¶ 4. Sarepta also directs and controls the manufacture (or making) of golodirsen in the United States [REDACTED]

[REDACTED] SOF ¶¶ 11-13. In view of these facts, it is indisputable that Sarepta directly infringes the NS Product Claims. SOF ¶ 23. Indeed, neither Sarepta nor its expert have identified any contention that Sarepta does not directly infringe the NS Product Claims. SOF ¶ 24. And Sarepta's counsel has stated that Sarepta is willing to withdraw its defense of non-infringement. SOF ¶ 32. Summary judgement of direct infringement of the NS Product Claims is warranted.

B. Sarepta Indirectly Infringes the NS Product and NS Method of Use Claims

A party induces infringement under 35 U.S.C. § 271(b) if it “knowingly induce[s] [another party's] infringing acts, and possesse[s] a specific intent to encourage another's infringement.” *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1328 (Fed. Cir. 2009). A party contributes to infringement under 35 U.S.C. § 271(c) if it offers to sell or sells a “component of a patented [invention]” that constitutes a “material part of the invention” and is “especially adapted for use in infringement” without any “substantial noninfringing use.” 35 U.S.C. § 271(c). Both induced and

contributory infringement require “knowledge of the patent in suit and knowledge of patent infringement.” *Commil USA, LLC v. Cisco Sys.*, 575 U.S. 632, 639 (2015).

Just as the making and use of Vyondys 53[®] directly infringes the NS Product Claims (*see* § A, *supra*), it is also undisputed that the use of Vyondys 53[®] directly infringes the NS Method of Use Claims. SOF ¶¶ 5-10, 14-16, 27. Sarepta has provided no rebuttal. SOF ¶ 28. The evidence also shows that Sarepta [REDACTED], and [REDACTED]—and certainly well before Sarepta filed IPRs on each of them in June 2021. SOF ¶¶ 17-20. [REDACTED], it also cannot dispute knowledge of infringement. SOF ¶¶ 24, 31-32. With this knowledge, Sarepta encouraged another party to infringe the NS Product Claims [REDACTED] SOF ¶¶ 11-12. Sarepta also encouraged medical professionals to infringe the NS Product and Method of Use Claims by administering Vyondys 53[®] (golodirsen) in accordance with Sarepta’s prescribing instructions. SOF ¶¶ 14-16. Finally, Sarepta sold and offered to sell golodirsen—a material part of the NS Product and Method of Use Claims that has no noninfringing use. SOF ¶¶ 4, 16.

Accordingly, it is undisputed that Sarepta indirectly infringes the NS Product and NS Method of Use Claims under 35 U.S.C. § 271 (b) and (c). Indeed, neither Sarepta nor its expert have identified any contention that Sarepta does not indirectly infringe the NS Product and NS Method of Use Claims. SOF ¶ 31. And Sarepta’s counsel has stated that Sarepta is willing to withdraw its defense of non-infringement. SOF ¶ 32. Summary judgement of indirect infringement of the NS Product Claims and NS Method of Use Claims is warranted.

VII CONCLUSION

The Court should find that Sarepta has infringed the NS Product Claims under 35 U.S.C. § 271 (a), (b) and (c), and the NS Method of Use Claims under 35 U.S.C. § 271 (b) and (c).

Dated: December 11, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that on December 11, 2023, a copy of the foregoing, which was filed under seal, was served via electronic mail on the following counsel of record:

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